UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,257	04/23/2001	Robert A. Scott	6512-11EJF	7160

29668 7590 07/27/2005

PFIZER, INC.
201 TABOR ROAD
MORRIS PLAINS, NJ 07950

EXAMINER	
HON, SOW FUN	
ART UNIT	**PAPER NUMBER**
1772	

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/840,257	SCOTT ET AL.	
	Examiner	Art Unit	
	Sow-Fun Hon	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-61,63-65,67-71 and 73-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-61,67-71 and 73-81* is/are rejected.

7)☒ Claim(s) *63-65* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Rejections Withdrawn

1. The 35 U.S.C. 103(a) rejections have been withdrawn due to the amendment dated 04/19/05.

New Rejections

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 57-61, 63-65, 67-71, 73-81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of US 6,517,865 in view of US 3,664,963. '865 fails to claim polyvinyl alcohol in place of cellulose ether as the bulk polymer material.

'963 teaches a method for providing a capsule (column 1, lines 29-31), wherein the encapsulating composition can be polyvinyl alcohol in place of cellulose derivatives (ethers and esters, column 3, lines 1-14).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have claimed polyvinyl alcohol in place of the cellulose ether, which is a cellulose derivative claimed by '865, in order to claim a capsule with the advantages of the physical properties of polyvinyl alcohol, as taught by '963.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 57, 60-61, 67-71, 73-78, 80-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. (US 5,264,223) in view of Pasin (US 3,664,963).

Regarding claims 57, 67-68, 70, 81, Yamamoto teaches a capsule comprising a film-forming polymer (cellulose ether) and a setting system (gelatinizing agent, abstract). Yamamoto teaches that the setting agents are polysaccharide hydrocolloids such as kappa-carrageenan (column 3, lines 1-10) and the cations (auxiliary potassium ion, ammonium ion or calcium ion, column 3, 10-20). Yamamoto teaches that the amount of film-forming polymer (water soluble cellulose derivative) is 92 to 94 % by weight (column 4, lines 30-35), which is within the claimed range of 90 to 97 %, the amount of hydrocolloid (setting (gelatinizing) agent) is 0.1 to 0.5 % by weight, which is

within the claimed range of 0.01 to 10 %, the amount of cation (auxiliary) is 0.01 to 0.5 % by weight (column 4, lines 26-36), which is within the claimed range of 0.001 to 5 %, and the amount of water is 4 to 6 % by weight of the capsule film (column 4, lines 35-40), which is within the claimed range of 2 to 7 % based on the total weight of the capsule, in order to obtain a good hard capsule film via dip molding (conventional immersion molding method) (column 4, lines 15-20).

Yamamoto fails to teach that the film-forming polymer of the specific capsule composition is polyvinyl alcohol instead of cellulose ether.

Pasin teaches a method for providing a capsule (column 1, lines 29-31), wherein the encapsulating composition can be polyvinyl alcohol in place of cellulose derivatives (ethers and esters, column 3, lines 1-14).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have used polyvinyl alcohol as the film-forming polymer in place of the cellulose ether of Yamamoto, in order to take advantage of the physical properties of polyvinyl alcohol, as taught by Pasin.

Regarding claims 60-61, Yamamoto teaches the formation of the capsule by immersion of a moulding pin into a solution of the composition (column 4, lines 1-10). Although Yamamoto fails to teach that the capsule comprises two halves sealed together by a liquid fusion process, the resultant capsule is still the same. Even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is

the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985).*

Regarding claim 67-70, Yamamoto teaches that the setting agents are polysaccharide hydrocolloids such as kappa-carrageenan (column 3, lines 1-10) and polysaccharides of tamarind gum (seed) and curdlan (column 3, lines 1-4).

Regarding claims 71, 73-77, Yamamoto teaches that plasticizer and coloring agent (dye or pigment) may be added to the capsule composition, as taught in the prior art (column 1, lines 15-20). Hence the amounts of plasticizer and coloring agent can be 0, which meet the lower end of the claimed range of from about 0 to 40 % plasticizer (claim 71) and the lower end of the claimed range of from about 0 to 10 % of coloring agent (claim 74).

Regarding claim 78, Yamamoto teaches a hard capsule (column 4, line 26).

Regarding claim 80, Yamamoto teaches a method of manufacturing a capsule comprising a) forming an aqueous solution comprising 5 to 25 % by weight of film-forming cellulose derivative, which overlaps the claimed range of 10 to 60 %, 0.10 to 5 % by weight of setting agent (gelatinizing agent), which overlaps the claimed range of 0.10 to 5 % by weight and 0.01 to 0.5 % by weight of cation (auxiliary for gelation, column 3, lines 20-30), which overlaps the claimed range of 0.001 to 3 %, and b) immersion molding (column 4, lines 1-10), which is the same as dip molding, the aqueous solution to form the capsule. Yamamoto teaches that the setting agents are

polysaccharide hydrocolloids such as kappa-carrageenan (column 3, lines 1-10) and the cations (auxiliary potassium ion, ammonium ion or calcium ion, column 3, 10-20).

6. Claims 58-59, 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto in view of Pasin as applied to claims 57, 60-61, 67-71, 73-78, 80-81 above, and further in view of Deters et al. (US 4,627,850).

Yamamoto in view of Pasin teaches a capsule comprising 90 to 97% by weight of a polyvinyl alcohol, 2 to 7% by weight of water, a setting system comprising 0.01 to 10 % by weight of a hydrocolloid of mixtures thereof, and 0.001 to 5 % by weight of cations based on the total weight of the capsule, as described above.

Regarding claims 58-59, Yamamoto in view of Pasin fails to teach that the capsule has at least one coating thereon, let alone that it is made from a substance selected from cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, hydroxyalkyl methylcellulose phthalate.

Deters teaches a capsule formed of polyvinyl alcohol (column 21, lines 44-49) which is a hydrophilic polymeric composition (column 5, lines 10-20), having at least one coating thereon (encapsulated with a semipermeable polymeric material, column 5, lines 5-8) is made from a substance selected from cellulose acetate phthalate and hydroxypropyl methylcellulose phthalate which is a species of hydroxyalkyl methylcellulose phthalate (column 8, lines 50-60). Deters teaches that the coating is enteric (column 8, lines 45-50). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have coated the capsule of Yamamoto in view of Jansen, with an enteric coating such as cellulose acetate

phthalate or hydroxypropyl methylcellulose phthalate, in order to obtain a capsule with the desired release characteristics, as taught by Deters.

Regarding claim 79, Yamamoto in view of Pasin fails to teach a soft capsule. Deters teaches that a hard capsule and a soft capsule are two embodiments of the same invention (column 3, lines 49-55). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided an alternate embodiment of the capsule of Yamamoto in view of Pasin in the form of a soft capsule for the desired end-use, as taught by Deters.

Allowable Subject Matter

7. Claims 63-65 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The closest cited prior art of record, US 5,264,223 fails to teach, even in combination with US 3,664,963 and US 4,627,850, the combination of a capsule comprising 90 to 97 % by weight of a polyvinyl alcohol, 2 to 7 % by weight of water, a setting system comprising 0.01 to 10 % by weight of a hydrocolloid or mixtures thereof and a sequestering agent selected from the group consisting of ethylenediaminetetraacetic acid, acetic acid, boric acid, citric acid, edetic acid, gluconic acid, lactic acid, phosphoric acid, tartaric acid or salts thereof, metaphosphates, dihydroxyethylglycine, lecithin, beta cyclodextrin and combinations thereof, and 0.001 to 5 % by weight of cations, based on the total weight of the capsule. There is no teaching of a sequestering agent selected from the group consisting of

ethylenediaminetetraacetic acid, acetic acid, boric acid, citric acid, edetic acid, gluconic acid, lactic acid, phosphoric acid, tartaric acid or salts thereof, metaphosphates, dihydroxyethylglycine, lecithin, beta cyclodextrin and combinations thereof.

Response to Arguments

8. Applicant's arguments with respect to claims 57-61, 63-65, 67-71, 73-81 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (571)272-1492. The examiner can normally be reached Monday to Friday from 10:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached at (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Hon

Sow-Fun Hon

07/22/05

HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

7/25/05